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Takeshi Saika

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EXAMINER

DESAI, ANISH P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,794	Applicant(s) SAIKA ET AL.	
	Examiner Anish Desai	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 11, 13-15, 18 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 11, 13-15 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments in response to the Office action dated 12/28/06 have been fully considered.
2. Claims 1, 5-10, 12, 16, 17, and 19 are cancelled. Claims 2-4, 11, 13-15, 18, and 20-30 are pending. Claims 25-30 are newly added claims.
3. The 35 USC Section 112 second paragraph rejection to claims 11 and 23 (mistakenly referred to as claim 22 in the previous Office Action) are withdrawn in view of the present amendment and response.
4. A new 35 USC Section 112 first paragraph rejection is made.
5. All of the art rejections are maintained. The Examiner has previously provided a machine language translation for JP 2002-142797 to Takeshi. However instead of using the machine translation, a new English translation of the JP reference is provided herein for clarity.
6. A new 35 USC Section 103 rejection is made over Takeshi et al. (JP 2002-142797) in view of Lorincz (US 5,812,312) and Vesey et al. (US 6,225,046B1).

Election/Restrictions

7. Newly submitted claims 25-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 25-30 are directed to method of testing for microorganisms. Applicant has previously received an action on merits for article claims. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-30 are

withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2, 11, 21, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regards to claims 2 and 21, the newly added claim limitation of “a layer free of the focusing marker” is a negative limitation. The specification does not provide explicit support for this limitation as presented. Page 8 of the specification states that the focusing marker can be applied to the substrate in a number of ways including providing a layer containing a focusing marker and laminating it to the substrate. This is recited in positive form and provides for less ambiguity and interpretation than is what is currently provided. Support for such a limitation with respect to the adhesive layer is only provided in an example (example 3). However, equivalent language such as that set forth with respect to the substrate would be considered appropriate and not constitute new matter or ambiguity.

Regarding claims 11 and 23, the specification does not provide support for the newly added claim limitation of “with a different color from the background color of the field of a microscope or optical equipment with focusing function.” The disclosure at page 8 supports having a color variation in the print: “and more preferably has a color variation in the image used for focusing”, but does not seem to support language as specific as recited currently: “different color from the background color”. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 13, 20, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeshi et al. (JP 2002-142797) (English translation provided by the examiner) in view of Lorincz (US 5, 812, 312).

Regarding claims 2 and 21, Takeshi discloses a pressure-sensitive adhesive sheet (adhesive sheet) and a kit for testing microorganisms on solid surface (0008-0011, page 4). The kit of Takeshi comprises an adhesive sheet having a pressure-sensitive adhesive layer on a substrate (0014 page 5) and an aqueous solution containing one or more colorizing materials (color-developing substances) that can stain microorganisms (0011 page 4). Further, according to Takeshi “As a result of an intense study... we have attained the present invention using a microorganism test pressure-sensitive adhesive sheet having an pressure-sensitive adhesive layer...with

pressing to and peeling from the test specimen surface of the pressure-sensitive adhesive layer to accumulate microorganisms, followed by detection of microorganisms” (0008 page 4). The detection of microorganisms is performed by a microscope (see 0029 page 9). This disclosure of Takeshi reads on “wherein the adhesive layer comprises an exposed surface...subjected to image analysis under a microscope or optical equipment”. Additionally, Takeshi discloses that the substrate can be polyethylene-laminated paper (0014 page 5), which reads on “where the substrate is a multilayer” as claimed.

The difference between the prior art of Takeshi and the presently claimed invention is that Takeshi is silent with respect to teaching wherein the substrate or the adhesive layer is a multilayer including a layer comprising the focusing marker and a layer free of the focusing marker, the focusing marker comprises insoluble particles. However, Lorincz discloses a self-staining microscopic slide designed for immediate staining and viewing cells in biological fluids and tissue samples. Further the slide of Lorincz can include reference standards to facilitate microscope focusing and to allow measurements of cells and microorganisms (abstract). The invention of Lorincz includes a film 16 having an adhesive on one side, for placement of film on the surface of the slide (column 4 lines 19-23). Lorincz teaches that it is beneficial to include size references such as fluorescent microspheres of known dimension (e.g. 1 μm) to the surface of the slide or the film such that they coincide with the field of focus of the specimen. According to Lorincz, this facilitates the focusing the microscope and provides an internal reference standard for size, which is preserved for

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photomicrography or video image capture (column 4, lines 32-45). Although, Lorincz does not explicitly teach that the microspheres are insoluble, it is reasonable to presume that the microspheres of Lorincz are insoluble because soluble particles cannot be used as a reference standard (focusing marker) to focus the microscope. Additionally, Lorincz discloses that the microspheres may be placed in a dye before the application of the dye to the slide such that they are held to the slide with the subsequently dried dye (column 4 lines 38-39). Hence, the dye does not solvate the microspheres of Lorincz and thus they are insoluble. This disclosure meets the claim requirement of insoluble particles. Further, as to claim requirement of a layer free of the focusing marker, the microspheres of Lorincz are attached either to the film or to the adhesive on the film, therefore Lorincz discloses a layer free of focusing marker. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the microspheres (focusing marker) of Lorincz in the multilayer substrate of the adhesive sheet of Takeshi, motivated by the desire to facilitate the focusing of the microscope such that microorganisms can be accurately detected and/or counted.

The claim requirements of (a) and (b), only one of the requirement needs to be met in order to reject the claim, because either the substrate **OR** the adhesive is multilayer as recited in claim. Since the substrate of Takeshi as modified by Lorincz is a multilayer substrate, and the adhesive sheet and the kit of Takeshi as modified by Lorincz has the same structure as Applicant's claimed adhesive sheet and the kit, the layer comprising focusing marker would necessarily contact the adhesive layer.

Regarding claims 13 and 24, Takeshi discloses that in counting captured microorganisms using a microscope, for focusing on the microorganisms collected on the adhesive layer, the surface smoothness (undulation) should be below 20 micrometer so that the focusing range is expanded, making the counting easier (0016 page 6).

10. Claims 3, 4, 14, 15, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeshi et al. (JP 2002-142797) (English translation provided by the examiner) in view of Lorincz (US 5, 812, 312) as set forth above, and further in view of Vesey et al. (US 6,225,046B1).

The invention of Takeshi as modified by Lorincz is previously disclosed. Takeshi as modified by Lorincz is silent with respect to teaching particle size of 2.0 to 200 μm . However, Vesey discloses methods for detecting microorganisms in a sample by binding detectable particles and fluorescent-labeled ligands reactive to the microorganisms (abstract). The particles of Vesey are fluorescent particles and have a diameter of 10 nm to 0.1 mm, which converts to 0.01 μm (1 nm = 0.001 μm) to 100 μm (1 mm = 1000 μm) respectively. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the focusing marker comprising the particles with the size as claimed in the presently invention, as it is known that a varied size of marker particle is useful depending on the size of the object desired to be observed.

11. Claims 11, 18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeshi et al. (JP 2002-142797) (English translation provided by the Examiner) in view of Lorincz (US 5, 812, 312) as set forth above, and further in view of Herauf (US 5,085,937).

Lorincz as modified by Takeshi is silent as to teaching of the focusing marker is an undulation pattern of 0.1 to 20 μm depth or a printed pattern with a color variation and with a different color from the background color of the field of a microscope or optical equipment with focusing function. However, Herauf teaches a particulate monitoring tape to determine the amount of particulate matter, which has settled on the tape surface (abstract). Additionally, Herauf discloses of printing a grid pattern using black ink on the surface of the backing layer (substrate) (column 2, lines 39-42 and claim 4) such that the tape can be used to collect and analyze particulates under microscope (column 4, lines 23-28). Further, Herauf discloses that if the tape is to be used in an area where airborne particles are likely to be of a lighter color, then coating 16 should incorporate a black pigment and lines (of the grid) 20 would be white. Thus, this arrangement of the black pigment and white line reads on the color variation as required by the presently claimed invention. According to Herauf, after sampling a surface using the adhesive tape of his invention, the tape is placed under the microscope for viewing and counting the number of particulates (column 4 lines 23-25). The particulate level is determined according to the average number of particulates in a given square formed by the grid pattern (abstract). Thus, it is the Examiner's position that the grid pattern as taught by Herauf functions as a focusing marker. As to the claim

limitation of focusing marker with a color different from the background color of the field of a microscope, it would have been obvious to provide a focusing marker with a color different from the background color of the field of the microscope, in order to successfully distinguish the focusing marker from the background color in order to be able to focus the microscope. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the printed grid pattern as taught by Harauf in the invention of Takeshi, motivated by the desire to simplify the determination of the number and/or size of microorganisms on the adhesive sheet.

Regarding claim 18, Takeshi discloses that in counting captured microorganisms using a microscope, for focusing on the microorganisms collected on the adhesive layer, the surface smoothness (undulation) should be below 20 micrometer so that the focusing range is expanded, making the counting easier (0016 page 6).

Response to Arguments

12. Applicant's arguments filed on 05/29/07 have been fully considered but they are not persuasive.

Applicant argues that Lorincz does not teach or suggest a focus marker, which is contained within the substrate or adhesive multilayer as recited in claims 2, 21, and 25. The Examiner respectfully disagrees. Lorincz discloses "Other features which are beneficial include the addition of size references, such as fluorescent microspheres...to the surface of the slide or the film" (column 4 lines 32-36). The film of Lorincz, as

previously disclosed has an adhesive coated onto it. Thus, the film of Lorincz is equated to the substrate. Thus, the focusing marker is added to the substrate.

Applicant argues that Lorincz fails to teach or suggest focusing marker comprising insoluble particles. According to Applicant, Lorincz fails to teach or suggest insoluble particles such as calcium carbonate or cellulose powder particles employed in the present invention. The Examiner respectfully disagrees. While it may be true that Lorincz does not explicitly acknowledge that his particles (microspheres) are insoluble, it is reasonable to presume that the microspheres of Lorincz are insoluble because soluble particles cannot be used as a reference standard (focusing marker) to focus the microscope. If the particles were soluble then they would not serve its purpose of reference marker (i.e. focusing marker). Additionally, Lorincz discloses that the microspheres may be placed in a dye before the application of the dye to the slide such that they are held to the slide with the subsequently dried dye (column 4 lines 38-39). Hence, the dye does not solvate the microspheres of Lorincz and thus they are insoluble. As to the arguments with respect to particles of calcium carbonate or cellulose powder, this argument is not in commensurate in scope with the claims, because claims do not require that the insoluble particles be formed of calcium carbonate or cellulose powder.

Applicant argues that Herauf reference is not a focusing marker, because Herauf reference does not teach or suggest anything that the grid pattern of his invention can be used to facilitate focusing. The Examiner respectfully disagrees. Herauf discloses that after sampling a surface using the adhesive tape of his invention, the tape is placed

under the microscope for viewing and counting the number of particulates (column 4 lines 23-25). The particulate level is determined according to the average number of particulates in a given square formed by the grid pattern (abstract). Thus, if one wants to count particulates that are being sampled using the tape of Herauf, under the microscope, one would necessarily have to focus the microscope on to the grid pattern. Thus, the grid pattern acts as a focus marker even if such disclosure is not explicit.

Applicant argues that there is no teaching or suggestion in any of the references to modify their respective disclosures in the manner necessary to provide the present invention. According to Applicant, without at least recognizing the associated benefits (e.g. real time monitoring for the presence of microorganisms, accommodation of automated focusing etc.), one of ordinary skill in the art would not be motivated to modify the teachings of the references in order to arrive at the present invention. The Examiner respectfully disagrees. As to the argument that there is no teaching or suggestion in any of the references to modify their respective disclosure, the Examiner respectfully reminds Applicant that the teaching or suggestion to modify the reference does not have to be found in the references themselves and that the ruling in *KSR v Teleflex* specifically held that a teaching, suggestion or motivation is not required to show obviousness. Further as to the arguments regarding recognition of associated benefits of presently claimed invention, these arguments are not found persuasive because they are not in commensurate in scope with the claims and do not account for or refute the rationale for obviousness advanced by the Examiner. Please note 37 CFR 1.111(b). Accordingly, art rejections are maintained.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Desai whose telephone number is 571-272-6467. The examiner can normally be reached on Monday-Friday, 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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